PTCA Catheter Reclassification Panel Meeting

December 4, 2000

- Introductory Remarks (FDA)
- Petitioner Presentation
- Presentation of Questions for the Panel
- Completion of Reclassification Questionnaires

Lynette Gabriel FDA/CDRH/DCRD

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Regulatory History of PTCA Catheters

- First PMA received in 1979 and approved in 1980
- 20 original PMAs approved to date
  - most recent in 1999
- 820 PMA supplements approved
  - supplements often represent new models

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Devices Under Consideration

- Per proposed device description
  - *A PTCA balloon catheter has a single or double lumen shaft with a balloon near the distal tip. The catheter typically features a minimally compliant balloon constructed from a high density polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with acceptable rates of inflation and deflation and acceptable burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use.*

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Devices Under Consideration

- For proposed indication for use
  - *Intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion*

MAUDE Database Adverse Events

- Balloon Rupture
- Balloon Burst
- Device Breakage
- Deflation Difficulties
- Inflation Difficulties
- Insertion Difficulties
- Device or Fragments Remain in Patient
- Removal Difficulties
- Separation
- Sticking
- Tip Breakage

Comments Received

- Agree with proposal to downclassify PTCA catheters
- Reclassification should apply only to "standard" PTCA catheters
- Concern about the use of PTCA catheters to treat in-stent restenosis
- Suggestions for FDA guidance document

PTCA Catheter Reclassification

Questions for the Panel

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Proposed Device Description

A PTCA balloon catheter has a single or double lumen shaft with a balloon near the distal tip. The catheter typically features a minimally compliant balloon constructed from a high density polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with acceptable rates of inflation and deflation and acceptable burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use.

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Question for the Panel

- Does the proposed classification description sufficiently describe PTCA catheters?

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Proposed Risks to Health

- Acute Vessel Closure
- Dissection/Perforation
- Acute MI/Unstable Angina
- Coronary Artery Spasm
- Arrhythmia
- Embolization
- Hypotension/Hypertension
- Stroke
- Reaction to Contrast Agent
- Failed Procedure
- Coagulopathy
- Aneurysm Formation
- Vascular Access Site Complications
- Restenosis
- Emergency Bypass Surgery
- Death
- Balloon Rupture
- Guidewire Fracture/Entrapment

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Question for the Panel

- Have the health risks associated with PTCA catheters been adequately identified?
- If not, what are the additional risks that should be described?

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Proposed Special Controls

- **Guidance Document**
- **Device Labeling**

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Question for the Panel

- Have the appropriate special controls been identified to adequately address the risks to health specific to PTCA catheters?
- If not, what additional special controls are necessary to reclassify PTCA catheters?

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